

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

ADAM KANUSZEWSKI et al.,

Plaintiffs,

Case No. 1:18-cv-10472

v.

Honorable Thomas L. Ludington
United States District Judge

SANDIP SHAH et al.,

Defendants.

/

**OPINION AND ORDER DENYING DEFENDANTS' MOTIONS FOR CERTIFICATE
OF APPEALABILITY AND TO STAY CASE, AND VACATING ORDER IN PART**

On September 13, 2022, this Court granted Plaintiffs' motion for reconsideration, denied Defendants' motion for reconsideration, and vacated in part its prior order.

Defendants have since filed a motion for a certificate of appealability on three state-law statutory-interpretation issues and a motion to stay the case pending appeal of those three issues. Plaintiffs contest both motions.

The questions presented are whether those issues involve controlling questions of law, contain substantial grounds for difference of opinion, or would materially advance the case if immediately appealed.

I.

Plaintiffs are four parents of nine Michigan-born children who contend that the State of Michigan, four Michigan officials, and a private biobank and its director have violated the Fourth and Fourteenth Amendments by retaining, transferring, storing, selling, and using the children's blood samples (DBS) for research and other unspecified purposes without informed consent.

After the first round of dispositive motions, the Sixth Circuit reversed and remanded the case with specific instructions: “to apply strict scrutiny to any of Defendants’ conduct that lacked informed consent.” *Kanuszewski v. Shah*, No. 1:18-CV-10472, 2022 WL 4227875, at *4 (E.D. Mich. Sept. 13, 2022) (citations omitted); *see also Kanuszewski v. MDHHS*, 927 F.3d 396, 420–21 & 420 n.13 (6th Cir. 2019) (holding that Plaintiffs plausibly alleged Defendants’ retention, transfer, storage, and “future use by the state or third parties” was “undertaken without informed parental consent” and “must survive strict scrutiny”). To wit: (1) Did Defendants obtain Plaintiff-parents’ informed consent for the retention, transfer, storage, sale, or research of their children’s DBS? (2) If not, then does Defendants’ conduct survive strict scrutiny?

The reason that all Defendants’ conduct required informed consent, the Sixth Circuit held, is that “parents” have “a fundamental right . . . to direct the medical care of their children.” *Kanuszewski v. MDHHS*, 927 F.3d at 418–19. As the Sixth Circuit concluded on the issue, if Defendants “retain the samples, transfer the samples to the Neonatal Biobank, and store the samples indefinitely for further use by the state or third parties. . . . without informed parental consent,” then “Defendants’ actions constitute a denial of the parents’ fundamental right to direct the medical care of their children, and their actions must survive strict scrutiny.” *Id.* at 420. “[E]mphasiz[ing] that a fundamental right is at stake,” the Sixth Circuit added that this Court must determine whether the “nature” of “any parental consent that occurred” was “informed” and whether Defendants’ conduct fell within the “scope” of the informed consent. *Id.* at 420 n.13.

On remand, this Court followed the Sixth Circuit’s directive. *See Kanuszewski v. Shah*, 551 F. Supp. 3d 747, 766–68 (E.D. Mich. 2021) (applying strict scrutiny to Defendant’s conduct that lacked Plaintiffs’ informed consent), *vacated in part*, No. 1:18-CV-10472, 2022 WL 4227875 (E.D. Mich. Sept. 13, 2022).

Then, addressing the parties' cross-motions for reconsideration, this Court "explain[ed] why the applicable law requires Michigan's informed-consent standard in this case and then appl[ied] that standard to the parties' summary-judgment motions." *Kanuszewski*, 2022 WL 4227875, at *6. This Court held that all Defendants' conduct lacked informed consent under Michigan's informed-consent statutes.¹ *See id.* at *11–15.

Defendants have since requested a certificate of appealability for interlocutory appeal, ECF No. 215, and a stay pending appeal, ECF No. 217, both of which Plaintiffs contest, ECF Nos. 216; 218. As explained hereafter, both requests will be denied.

II.

In a civil case, a district judge may certify a nonfinal order for interlocutory appeal if "[1] the order involves a controlling question of law to which there is [2] substantial ground for difference of opinion and . . . [3] an immediate appeal may materially advance the termination of the litigation." *In re Trump*, 874 F.3d 948, 951 (6th Cir. 2017) (cleaned up) (quoting 28 U.S.C. § 1292(b)). These findings, "along with other prudential factors," guide the Sixth Circuit's discretion to permit an appeal of a district-court order. *Id.*

Defendants raise two questions:

- (1) whether Michigan's informed-consent statutes apply to Michigan's newborn screening program, and
- (2) whether Michigan's informed-consent statutes apply to Michigan's BioTrust program.

¹ There was an error in the prior order in holding that "there is a triable question of fact as to whether the parents of RFK, CKK, LRW, CJW, and HJW gave their informed consent to research." *Kanuszewski v. Shah*, No. 1:18-CV-10472, 2022 WL 4227875, at *15 (E.D. Mich. Sept. 13, 2022). The order should have read that "there is no genuine question of fact that the parents of RFK, CKK, LRW, CJW, and HJW did not give their informed consent to research." That portion of the prior order will be discussed and vacated *supra* Section II.A.2.

ECF No. 215 at PageID.5858–66.² To that end, as the parties note, there are three possible sources of informed consent: (1) Michigan Compiled Laws §§ 333.17020 and 333.17520, (2) 45 C.F.R. § 46.116(d) as referenced in Michigan Compiled Laws § 333.5431(7)(b), and (3) the constitutional “voluntary and knowing” requirements for waiver of fundamental rights.

A.

Interpreting a statute is a question of law. *See Smith v. Comm’r of Soc. Sec.*, 482 F.3d 873, 876 (6th Cir. 2007). Defendants’ questions both involve interpretations of Michigan Compiled Laws §§ 333.17020 and 333.17520, so they both involve questions of law.

Although Defendants invoke two “question[s] of law,” the questions are not “controlling.” A question of law is controlling if it could materially affect the outcome of the case. *In re City of Memphis*, 293 F.3d 345, 351 (6th Cir. 2002). Neither question could do so here.

1.

Defendants first assert their nonresearch posttesting use of the DBS did not require the Plaintiff-parents’ informed consent under § 333.17020, § 333.17520 or § 46.116(d). *See* ECF No. 215 at PageID.5858–63.

Defendants are incorrect. The Sixth Circuit mandated that this Court search for “informed consent to Defendants’ actions” and, if absent, then apply strict scrutiny. *Kanuszewski v. MDHHS*, 927 F.3d 396, 420–21 (6th Cir. 2019); *see also supra* discussion Part I. And this Court already found that Defendants’ nonresearch posttesting use of the DBS lacked informed consent under

² Notably, Michigan Compiled Laws § 333.5431(9) was improperly interpreted. Section 333.5431(8)(b) indicates that § 333.5431(9) allows *parents* to retain one DBS if the State offers to draw it. ECF No. 215 at PageID.5845 (arguing § 333.5431(9) does not “allow healthcare professionals and facilities to draw and provide, at a parent’s option, a blood spot to parents”). That is, § 333.5431(9) does not permit *Defendants* to draw an additional DBS for their own use. For this reason, ECF No. 214 will be vacated in part to the extent that it interprets or relies on § 333.5431(9). *See* ECF No. 214 at PageID.5822–24, 5829, 5831, 5833, 5834–35, 5839, 5841–42.

Michigan law and § 46.116. *Kanuszewski v. Shah*, 551 F. Supp. 3d 747, 763–65 (E.D. Mich. 2021) (holding that Defendants did not obtain informed consent under 45 C.F.R. § 46.116); *Kanuszewski v. Shah*, No. 1:18-CV-10472, 2022 WL 4227875, at *11–15 (E.D. Mich. Sept. 13, 2022) (same under Michigan Compiled Laws §§ 333.17020 and 333.17520).

As Defendants concede, if “there is no codified guidance, e.g., for use of DBS post-screening, given the law of this case, [then] strict scrutiny would apply.” ECF No. 218 at PageID.5932–33. Thus, if informed consent is not required under Michigan law or § 46.116, then the only remaining issue here is whether Defendant’s nonresearch posttesting conduct would survive strict scrutiny.

This Court has already found that Defendant’s nonresearch posttesting use of the DBS fails the strict-scrutiny analysis. *See Kanuszewski*, 551 F. Supp. 3d at 766–68 (holding that Defendants’ conduct failed strict scrutiny); *Kanuszewski*, 2022 WL 4227875, at *15–16 (same). Thus—regardless of whether the requirements of informed consent are grounded in Michigan law, § 46.116, or the Constitution—the outcome would be the same: Defendants did not obtain Plaintiffs’ informed consent for any nonresearch posttesting use of the DBS.

For these reasons, Defendant’s questions would have no material impact on the outcome of this case and are not controlling.

2.

The next issue is “whether the parents of RFK, CKK, LRW, CJW, and HJW gave their informed consent to *research*.” *Kanuszewski v. Shah*, No. 1:18-CV-10472, 2022 WL 4227875, at *15 (E.D. Mich. Sept. 13, 2022) (emphasis added).

Defendants add that the informed-consent provisions of 45 C.F.R. § 46.116 apply to the Biobank’s research. *Id.* at PageID.5864 (“Mich. Comp. Laws § 333.5431(7)(i) incorporates 45 C.F.R. § 46.116 by reference.”).

But, even if that is true, the Sixth Circuit mandated informed consent for Defendants’ posttesting research, too, as a matter of constitutional law. *Kanuszewski v. MDHHS*, 927 F.3d at 420–21. Thus, even if § 46.116 applies to Defendants’ research, the more rigorous constitutional requirements for informed consent must also apply.

This Court has already explained how Defendants’ research fails the IRB waiver provisions of § 46.116(d)—a much lower standard than informed consent. *Kanuszewski v. Shah*, 551 F. Supp. 3d at 763–65. And this Court has explained how the research-consent claims of RFK, CKK, LRW, CJW, and HJW failed the strict-scrutiny analysis. *Kanuszewski v. Shah*, 2022 WL 4227875, at *15–16. Yet this Court found a genuine question of fact as to whether Defendants’ research satisfied Michigan’s informed-consent statutes. *Id.*

On third look, Defendants also did not obtain Plaintiff-parents’ informed consent for research of the DBS of RFK, CKK, LRW, CJW, or HJW under § 333.17020 or § 333.17520. As explained, “Plaintiffs offer reliable expert testimony not only that Plaintiff-parents’ purported consent was constitutionally inadequate, but also that Defendants’ method for obtaining informed consent is constitutionally inadequate.” *Kanuszewski v. Shah*, 2022 WL 4227875, at *14 (internal citations omitted). And “Plaintiff-parents contend they did not give their informed consent,” that “their consent was not voluntary because they signed the forms a mere 24 hours after Plaintiff-mothers gave birth,” and “that Defendants did not explain the meaning of ‘research,’ that the DBS are sold, that private companies have access to the DBS, or how the DBS can be used to target certain demographics of babies and to reveal the identity of the respective baby.” *Id.* (internal

citations omitted). The only evidence to the contrary was “the informed-consent form’s reference to ‘[p]lease read’ a booklet.” *Id.* at *15. Although “that argument fails because the forms neither demonstrate whether the parents actually read the booklet nor give the parents the opportunity to confirm their understanding of the booklet’s contents,” *id.*, this Court erroneously found a question of fact based on the insufficient booklet reference, *id.* This Court will now *sua sponte* vacate that holding, which should have been resolved in Plaintiffs’ favor, because there is no genuine question of fact that Defendants did not obtain Plaintiff-parents’ informed consent to conduct research on the DBS of RFK, CKK, LRW, CJW, or HJW under § 333.17020 or § 333.17520.

The same is equally true under 45 C.F.R. § 46.116’s lesser standard for informed consent. As relevant, § 46.116 required Defendants to give Plaintiff-parents sufficient opportunity to consider participation, to minimize the possibility of coercion or undue influence, and to provide the following information at a minimum:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject; and
- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

45 C.F.R. § 46.116(a) (2005). When appropriate, Defendants must also provide:

- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- (3) Any additional costs to the subject that may result from participation in the research;
- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- (6) The approximate number of subjects involved in the study.

45 C.F.R. § 46.116(b) (2005).

The informed-consent forms of RFK, CKK, LRW, CJW, and HJW did not provide the (1) purposes of the research, (2) expected duration of participation, (3) procedures to be followed, (4) identification of any experimental procedures, (5) foreseeable risks or discomforts, (6) possible benefits of the research, or (7) extent to which record confidentiality will be maintained. *See* ECF Nos. 147-15 at PageID.4315 (RFK); 147-16 at PageID.4309 (CKK); 147-18 at PageID.4313 (LRW); 147-19 at PageID.4315 (CJW); 147-20 at PageID.4317 (HJW); *Kanuszewski v. Shah*, No. 1:18-CV-10472, 2022 WL 4227875, at *14-15 & n.9 (E.D. Mich. Sept. 13, 2022); *see also* 45 C.F.R. § 46.116(a)(1), (2), (3), (5). All this is in addition to the above-described evidence that demonstrates a lack of informed consent under Michigan law.

That is, whether informed consent for research is analyzed under Michigan law or 45 C.F.R. § 46.116, there is no genuine question of fact that it lacks informed consent and fails strict scrutiny.

B.

Neither issue would give rise to a “substantial ground for difference of opinion.” 28 U.S.C. § 1292(b).

“A substantial ground for difference of opinion exists [if] reasonable jurists might disagree on an issue’s resolution, not merely [if] they have already disagreed.” *Reese v. BP Expl. (Alaska) Inc.*, 643 F.3d 681, 688 (9th Cir. 2011). Specifically, such a difference might exist if:

- (1) the question is difficult, novel, and either a question on which there is little precedent or one whose correct resolution is not substantially guided by previous decisions;
- (2) the question is difficult and of first impression;
- (3) a difference of opinion exists within the controlling circuit; or
- (4) the circuits are split on the question.

Newsome v. Young Supply Co., 873 F. Supp. 2d 872, 876 (E.D. Mich. 2012) (collecting cases).

There is only one case in the Sixth Circuit that directly addresses the issue that was before this Court when it issued the December 9, 2021 order: *Kanuszewski v. MDHHS*, 927 F.3d 396 (6th Cir. 2019).

And that case is not only the law of the case but also controlling precedent. That case substantially guided the resolution of this case. *See* discussion *supra* Sections I, II.A. The *Kanuszewski* court directed this Court to apply informed consent to Defendants’ conduct on remand. In this way, the question of informed consent is not a matter of first impression. Informed consent applies to all Defendants’ conduct because, as the Sixth Circuit explained, parents’ fundamental right to direct the medical care of their children entails a fundamental right to informed consent. Thus, Plaintiffs had the fundamental right to give and to refuse informed consent for Defendants’ conduct—all of it. Granted, the Sixth Circuit did not illuminate the source of informed consent, but that is inconsequential here, as explained above. Defendants’ conduct failed

under any possibly applicable informed-consent standard. And it all most clearly failed the strict-scrutiny analysis.

The only way that informed consent would not be required of Defendants' conduct is if the Sixth Circuit had some interest in *en banc* review of parents' fundamental liberty interest in refusing informed consent for their children's medical care. But Defendant has not attempted to demonstrate that the Sixth Circuit has any interest in hearing that issue *en banc*.

For these reasons, there is no "substantial ground for a difference of opinion." *In re Trump*, 874 F.3d 948, 951 (6th Cir. 2017).

C.

Nor would the petition "materially advance the termination of the litigation." *Id.* at 952 (quoting 28 U.S.C. § 1292(b)).

An interlocutory appeal would materially advance the litigation if it would "save judicial resources and litigant expense." *W. Tenn. Chapter of Associated Builders & Contractors, Inc. v. City of Memphis*, 138 F. Supp. 2d 1015, 1026 (W.D. Tenn. 2000). The "materially advance" requirement "is closely tied to the requirement that the order involve a controlling question of law." *City of Dearborn v. Comcast of Mich. III, Inc.*, No. 08-10156, 2008 WL 5084203, at *3 (E.D. Mich. Nov. 24, 2008) (quoting *Philip Morris Inc. v. Harshbarger*, 957 F. Supp. 327, 330 (D. Mass. 1997)).

Discovery has completed. What remains, then, are three questions of fact for a bench trial. Granted, there will be a few witnesses, but the case is not complex and the proofs are not extensive. And the appeal Defendants seek would waste judicial resources and litigation expenses because, as explained, the issues raised are of no consequence to the merits of Defendants' liability. *See* discussion *supra* Sections II.A, II.B.

D.

Defendants seek to appeal issues that do not involve a controlling question of law, that do not lend to a substantial ground for difference of opinion, and that would not materially advance the termination of the litigation if appealed. For these reasons, Defendants' Motions will be denied, and a certificate of appealability will not be issued.

III.

Accordingly, it is **ORDERED** that Defendants' Motion for Certificate of Appealability, ECF No. 215, is **DENIED**.

Further, it is **ORDERED** that Defendants' Motion to Stay, ECF No. 217, is **DENIED**.

Further, it is **ORDERED** that the September 13, 2022 Opinion and Order, ECF No. 214, is **VACATED IN PART**, as demonstrated by the following table:

Claim	Plaintiffs	Status
Data-retention (Count IV)	All	Triable
Tested DBS-retention (Count IV)	All	Triable
Additional DBS-retention (Count IV)	All	Triable
Tested DBS—research (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—storage (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—transfer (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—sale (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—maintain and expand NSP (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—other posttesting State use (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—other posttesting private-party use (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—disposal (Count II)	Kanuszewskis (DWL, RFK, CKK); Laporte (MTL); Wiegand (LRW, CJW, HJW)	Summary Judgment for Plaintiffs
Tested DBS—disposal (Count II)	Laporte (EMO); Wiegand (MLW)	Summary Judgment for Defendants

Additional DBS—research (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—draw (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—storage (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—transfer (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—sale (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—future identification purposes (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—maintain and expand NSP (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—other State use (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—other private-party use (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—disposal (Count II)	Kanuszewskis (DWL, RFK, CKK); Laporte (MTL); Wiegand (LRW, CJW, HJW)	Summary Judgment for Plaintiffs
Additional DBS—disposal (Count II)	Laporte (EMO); Wiegand (MLW)	Summary Judgment for Defendants

This is not a final order and does not close the above-captioned case.

Dated: October 20, 2022

s/Thomas L. Ludington
THOMAS L. LUDINGTON
United States District Judge